

SEP 16 2004

510(K) SUMMARY

Duet™ system

510(k) Number K040591/51

Applicant's Name:

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Date Prepared:

July, 2004

Trade Name:

Duet™ System

Classification Name:

Automated cell-location device

Classification:

The FDA has classified Automated cell-locating device as class II devices (product code 81 JOY, Regulation No. 864.5260) and they are reviewed by the Pathology Panel.

Predicate Device:

- Duet™ System, manufactured by BioView, cleared under K030192
- BandView, manufactured by Applied Spectral Imaging, cleared under K012103.
- Human manual visualization by conventional microscope.

Performance Standards:

No performance standards have been established for such device under Section 514 of the Federal Food, Drug, and Cosmetic Act. However, the Duet™ system complies with the following voluntary standards:

- EN 61010-1
- EN 61326-1
- IEC 60601-1-4
- EN-1441: Medical devices – Risk Analysis.
- ISO 14971 Medical Devices-Risk Management

Indications:

The Duet™ System is an automated scanning microscope and image analysis system. It is intended for *in-vitro* diagnosis use as an aiding tool to the pathologist in the detection, classification and counting of cells of interests based on particular color, intensity, size, pattern and shape.

The Duet™ System is intended to detect the following cell types:

1. Hematopoietic cells stained by Giemsa stain, Immunohistochemistry or ISH (with bright field and fluorescent) prepared from cell suspension.
2. Amniotic cells stained by FISH (using direct labeled DNA probes for chromosomes X, Y, 13, 18, and 21).

Device Description:

The Duet™ System is a fully integrated imaging and scanning platform that automates time-consuming and difficult laboratory tasks of slide screening by making a significant reduction in time and labor currently required.

The Duet™ scans in high resolution and in full color cell samples at high speed both in bright light illumination and in fluorescent illumination.

Duet™ suggests classification of the cells according to their morphological features, their staining (Giemsa, IHC) and fluorescent signals, and allows the

user to quickly examine the results, correct them as needed and generate a report summarizing the sample's data. The unique feature of the Duet system allows the presents combined presentation of morphological and specific staining information of the same cell, for all the cells of the sample.

Substantial Equivalence:

Intended use

- The additional indication of amniotic fluid detection, claimed for the Duet™ System in addition to the previous cleared indications was already claimed for the predicate BandView system.
- Detection, classification and counting of amniotic fluid cells after FISH are routinely performed manually by cytogeneticist using conventional microscopes.

The Duet™ System employs the same procedures for the detection of amniotic fluid cells after FISH (using direct labeled DNA probes for chromosomes X, Y, 13, 18, and 21) as employed by human manual visualization using conventional microscopes. Additionally, the new amniotic fluid indication was supported by a comparative performance study demonstrating that the operation of the Duet™ System is effective and suitable for the distinction between normal and abnormal amniotic fluid cells in comparison to manual microscopy.

Technological characteristics

The current Duet™ System is the same system as the 510(k)-cleared Duet™ System to which only some non-significant changes were incorporated mainly to support its new intended use. No change in hardware specifications was incorporated.

The Duet™ system, like its predicate devices, is software controlled and includes features such as: acquisition of images, views, editing, relocation, enhancement capabilities, automatic/manual counting and classification, printing, export of images and backups.

The main changes incorporated to the Duet™ System software include the following:

1. An automatic fluorescent scanning of Amniocentesis slides. This option was incorporated in order to support the new indication of the system.
2. Scanning each field of view with several fluorescent filters instead of only one, generating and displaying a combined image for each field of view. The ability to scan each field with only one filter, as was possible with the cleared Duet™ System is still an option in the current device.

All other minor changes that were incorporated into the software as compared to the cleared Duet™ System are described in details in the System's User's Manual, and in the Duet™ System SRS and SDD documents.

The risks that may be associated with each change were analyzed and after application of the mitigation methods, were found to be acceptable. The mitigation methods employed to contain these risks are standard software process and implementation procedures.

The Duet™ System software as a whole was fully validated during its development process. The results of the comprehensive validation of the software are presented in the System Test Report document.

Performance studies were accomplished to validate that the software and the system as a whole comply with the new indication. The Performance characteristics of the Duet System are described in the following section.

Mode of Operation

Exactly as the cleared Duet™ System, the current Duet™ System provides two modes of operation:

- Automatic scanning: provides a gallery of targets that the system captures for all identified cells.
- Manual scanning: provides interactive control over the microscope. This enables a user-controlled scan of any slide under either bright field or fluorescent illumination.

The user of the current Duet™ Systems, enters the scan parameters, slide number, comments, and annotates the results in the same manner as done using the predicate devices and during standard human visualization of cytology slides. Similarly, final classification is performed by the operator.

Performance characteristics of the Duet System:

Performance characteristics of the Duet System were verified by the following studies:

1. Comparison of the routine manual method and the Duet method:

The NCCLS-EP9, *Method Comparison and Bias Estimation Using Patient Samples; Approved Guideline*, was used to determine accuracy.

A set of 133 slides of Amniotic fluid cells was prepared using direct labeled DNA probes for chromosomes X, Y, 13, 18, 21 (Vysis, Downers Grove, IL, USA) from samples of 68 ongoing pregnancies. These slides were examined by the routine manual method and by analysis using the Duet System.

Scatter plots for tested value versus the comparative value and bias plot of the deltas between the values of the Duet™ test and the manual method versus the values of the manual method were performed.

The correlation coefficient was 0.9843 with a slope of 0.9758 and an intercept of 2.2316.

Evaluation of precision performance within a system and across systems: NCCLS-EP5, Evaluation of Precision Performance of Clinical Chemistry Devices; Approved Guideline was used to determine precision. A set of four slides was analyzed, with each slides analyzed on three different systems and three times on one of these systems. The experiment was performed over a period of 14 days.

Intra-system precision showed no clinically significant differences with a Coefficient of Variation (CV) of 0.15%.

ANOVA was used to assess the differences between readings of the same slides by different systems compared to repeated readings of the same system. There were no clinically significant differences between the Duet™ System inter-system precision analyses.

Conclusion

The Duet™ system is substantially equivalent to the combination of the cleared Duet™ System, the BandView system and the human manual procedure of visualization by conventional microscope, in terms of intended use and Indications for Use. The Duet™ System is substantial equivalent in its technological characteristics and mode of operation to the cleared Duet™ System. Any minor differences in technological characteristics between the Duet™ System and its predicate devices do not raise new safety or effectiveness issues, based on the performance results and software validation.



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

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SEP 16 2004

Food and Drug Administration
2098 Gaither Road
Rockville MD 20850

Re: k040591
Trade/Device Name: Duet™ system
Regulation Number: 21 CFR 864.5260
Regulation Name: Automated cell-locating device
Regulatory Class: Class II
Product Code: JOY
Dated: July 06, 2004
Received: July 09, 2004

Dear Dr. Winitz:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

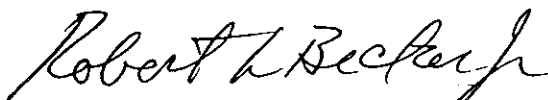
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in Title 21, Code of Federal Regulations (CFR), Parts 800 to 895. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Parts 801 and 809); and good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820). This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

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If you desire specific information about the application of labeling requirements to your device, or questions on the promotion and advertising of your device, please contact the Office of In Vitro Diagnostic Device Evaluation and Safety at (301) 594-3084. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address <http://www.fda.gov/cdrh/dsma/dsmamain.html>.

Sincerely yours,

A handwritten signature in black ink, reading "Robert L. Becker, Jr." in a cursive script.

Robert L. Becker, Jr., M.D., Ph.D.

Director

Division of Immunology and Hematology Devices

Office of In Vitro Diagnostic Device Evaluation and Safety

Center for Devices and Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K040591

Device Name: Duet™ System

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Prescription Use ✓
(Part 21 CFR 801 Subpart D)

AND/OR

Over-The-Counter Use _____
(21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of In Vitro Diagnostic Devices (OIVD)

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Division Sign-Off

Office of In Vitro Diagnostic
Device Evaluation and Safety

510(k) K040591